2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: November 13, 1998

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–30874 Filed 11–13–98; 3:10 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–0880]

Iceberg Water Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Iceberg Industries Corp. to market test a product designated as ''Borealis Iceberg Water'' that deviates from the U.S. standard of identity for bottled water. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility, in support of a petition to amend the standard of identity for bottled water.

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than February 16, 1999.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Iceberg Industries Corp., 447 Kenmount Rd., Box 13518, St. John's Newfoundland, Canada A1B 4B7.

The permit covers limited interstate marketing tests of products identified as ''borealis iceberg water'' that deviates from the U.S. standard of identity for bottled water (21 CFR 165.110) in that the source of the water is an iceberg. The test product meets all the requirements of the standard with the exception of the source definition. Because test preferences vary by area, along with social and environmental differences, the purpose of this permit is to test the product throughout the United States.

Under this temporary permit, the bottled water will be test marketed as ''Borealis Iceberg Water.''

This permit provides for the temporary marketing of 75,000 cases of the 24 x 350 milliliters and another 75,000 cases of the 12 x 1 liters (L), giving 150,000 cases in total. The total fluid weight of the test product will be 403,694 gallons or 1,530,000 L. The test product will be manufactured at Enterprise Atlantic Limited Water Bottling Plant, Daniel's Point, Trepassy, Newfoundland, Canada A0A 4B0. The product will be distributed throughout the United States.

The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101. This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than February 16, 1999.

Dated: November 5, 1998.

Elizabeth Campbell,

Acting Director, Office of Food Labeling, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–30607 Filed 11–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0946]

Expansion of Medical Device Industry Initiatives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) initiated a pilot program in 1996 involving the medical device industry. This pilot program, which was formally adopted in 1997, was shown to optimize resource utilization, enhance FDA/industry communication, and provide firms prompt closure to corrected inspection observations and nonviolative inspections. This program includes eligibility criteria and procedures for preannounced inspections, the annotation of items on form FDA–483–List of Observations (FDA–483) with promised or completed corrections, and postinspection notification to establishments regarding their compliance status.

DATES: The pilot program is effective January 1, 1999. Written comments should be submitted by January 4, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denise D. Dion, Office of Regulatory Affairs (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5645, FAX 301–443–6919.

SUPPLEMENTARY INFORMATION: During the FDA/medical device industry grassroots forums in 1995, several issues were discussed concerning FDA's interaction with the medical device industry. A decision was made to consider action on three of the issues discussed. These included instituting: (1) Preannounced inspections, (2) listing promised or completed corrective actions on FDA–483 items, and (3) postinspection notification to establishments regarding their compliance status.

After considering these issues, the agency decided to initiate a pilot program involving the medical device industry in fiscal year (FY) 1996. The pilot program occurred during the 1996 calendar year and was then formally evaluated. The pilot program included criteria and procedures for preannounced inspections, the annotation of FDA–483 items with promised or completed corrections, and postinspection correspondence.

The program was restricted to inspections of medical device manufacturers that manufactured only medical device products, and it did not include manufacturers of products that cross different program areas like devices/drugs/biologics.